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### **Program Office Perspective: Thoracic Coarse Particles**



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### **Overview**

- Basis for current standards (proposed vs. final decisions)
- Revised NAAQS review process
- Current PM NAAQS review
  - Key policy-relevant issues
  - Completed/ongoing activities
  - Schedule



# **Current PM NAAQS**

	2006 St	tandards
	Annual	24-hour
PM <sub>2.5</sub>	15 μg/m³ Annual average	<b>35 µg/m³</b> 98 <sup>th</sup> percentile
PM <sub>10</sub>	Revoked	150 µg/m³ 1 expected exceedance



# Summary of Data Available in Last Review

- Health effects evidence
  - Dosimetry data showed deposition of coarse particles in sensitive regions of the lung
  - Toxicology data showed potential mechanisms for coarse particles, or components, to affect respiratory system
  - Epidemiology data showed evidence of effects from short-term exposure to PM<sub>10-2.5,</sub> with supportive evidence from PM<sub>10</sub> studies where coarse fraction predominates
- Health risks estimated to occur in areas that did not meet current PM<sub>10</sub> standards; reasonably judged to be important from a public health perspective
- CASAC unanimously recommended a standard targeted to address particles between 2.5 and 10 µm



### Risk Assessment Conducted for Last Review

- Scope of quantitative risk assessment (QRA) conducted for PM<sub>10-2.5</sub> much more limited than QRA for PM<sub>2.5</sub>
  - 3 urban areas (Detroit, Seattle, St. Louis) and
  - 2 categories of health endpoints
    - Hospital admissions for cardiovascular and respiratory causes
    - Respiratory symptoms
- Staff judged QRA too limited to provide an appropriate basis for selecting level of standard for thoracic coarse particles

# Thoracic Coarse PM: Proposed Approach in '06

- Sufficient information was available to develop indicator for coarse particles based on the size fraction from 10 to 2.5 µm to replace PM<sub>10</sub> indicator
- Most obvious choice was size-differentiated, mass-based indicator used in epi studies that provided most direct evidence of health effects: PM<sub>10-2.5</sub>
  - Insufficient information available to define an indicator solely in terms of other metrics, such as specific chemical components
- Health effects evidence largely drawn from studies conducted in urban environments; largely an absence of evidence related to coarse particles typical of non-urban areas
- CASAC advised, and EPA pursued, an indicator that would focus regulation on urban-type coarse particles
  - Because evidence was insufficient to support compositionally based indicator, EPA focused instead on coarse particles associated with sources typical of urban environments, including high-density traffic on paved roads and industrial and construction sources

## Thoracic Coarse PM: Proposed Decision '06 – 24-Hr Standard

- Proposed qualified PM<sub>10-2.5</sub> indicator to focus on particles of concern:
  - Included "any ambient mix of PM<sub>10-2.5</sub> dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources"
  - Excluded "any ambient mix of PM<sub>10-2.5</sub> dominated by rural windblown dust and soils and PM generated by agricultural and mining sources"
  - Also stated that "Agricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting this standard"
- Proposed site suitability requirements for NAAQS-comparable monitors ("5-point test")
  - Urbanized Area with population >100,000;
  - Population density of block group > 500 (highly correlated with VMT; "may be" associated with industrial and construction sources);
  - Population-oriented monitoring site;
  - Not within micro-scale environment affected by a large source; and
  - Affirmative showing that mix within an area meeting above criteria is dominated by sources of concern

### Thoracic Coarse PM: Final Decision '06 - 24-hr Standard

- Retained existing 24-hour PM<sub>10</sub> standard of 150 µg/m<sup>3</sup> (first set in 1987)
- Problems with proposed "qualified" PM<sub>10-2.5</sub> indicator:
  - Inability to identify which particles were included/excluded
  - Proposed indicator failed to provide uniform national protection from particles of concern because of monitoring site suitability criteria
  - Evidence linked coarse particles in urban areas to adverse health effects, but was inconclusive regarding effects of thoracic coarse particles in rural areas
- PM<sub>10</sub> indicator determined to be more effective in targeting protection than other options
  - Inclusion of PM<sub>2.5</sub> provides variation in allowable PM<sub>10-2.5</sub> concentrations, allowing lower levels where concern is greater
  - "Double regulation" of PM<sub>2.5</sub> serves a valid purpose
  - Important to provide some protection from all thoracic coarse particles while targeting protection at urban and industrial mixes
  - Ensures inclusion of all ambient mixes of known concern; potential that research may reveal risks of non-urban or rural mixes

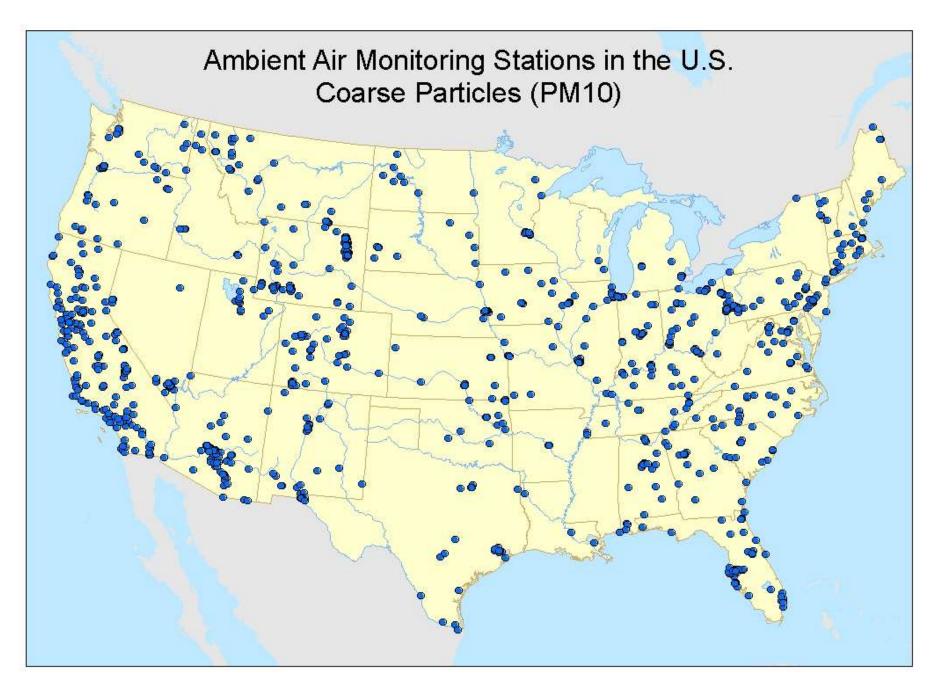
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### Thoracic Coarse PM: '06 - Annual Standard

- Proposed and finalized revocation of PM<sub>10</sub> annual standard
  - Available evidence did not suggest a link between long-term exposure to PM<sub>10</sub> at current ambient levels and health problems
  - Analysis of air quality data showed that the 24-hour PM<sub>10</sub> standards generally resulted in annual average PM<sub>10</sub> levels at or below the level of the former annual standard of 50 μg/m<sup>3</sup>

# PM<sub>10-2.5</sub> Monitoring Network Requirements

- New PM<sub>10-2.5</sub> Federal Reference Method (FRM) promulgated in '06
  - To support health research studies
  - To provide a basis for Federal Equivalent Methods (FEMs)
- Coarse particle measurements will be required at 75 NCore locations starting on Jan 1, '11
  - Measuring multi-pollutants in addition to coarse particles
  - ~55 Urban Sites at Neighborhood to Urban Scale
  - ~20 Rural Sites at Regional Scale
  - 1 in 3 day sampling
  - ~25 sites will measure coarse particle components



# **Potential NCORE Sites**



# Revised NAAQS Process: Key Steps

### • Planning:

- Receive early input from experts, including CASAC
- Focus efforts on key policy-relevant issues and science that informs our understanding of these issues
- Create one integrated plan early in process

### Integrated Science Assessment

- Replace voluminous Criteria Document with more concise synthesis of most policy-relevant science accompanied by extensive Annexes
- Develop continuous survey/evaluation of new science; create state-of-the-art electronic databases to catalog new studies

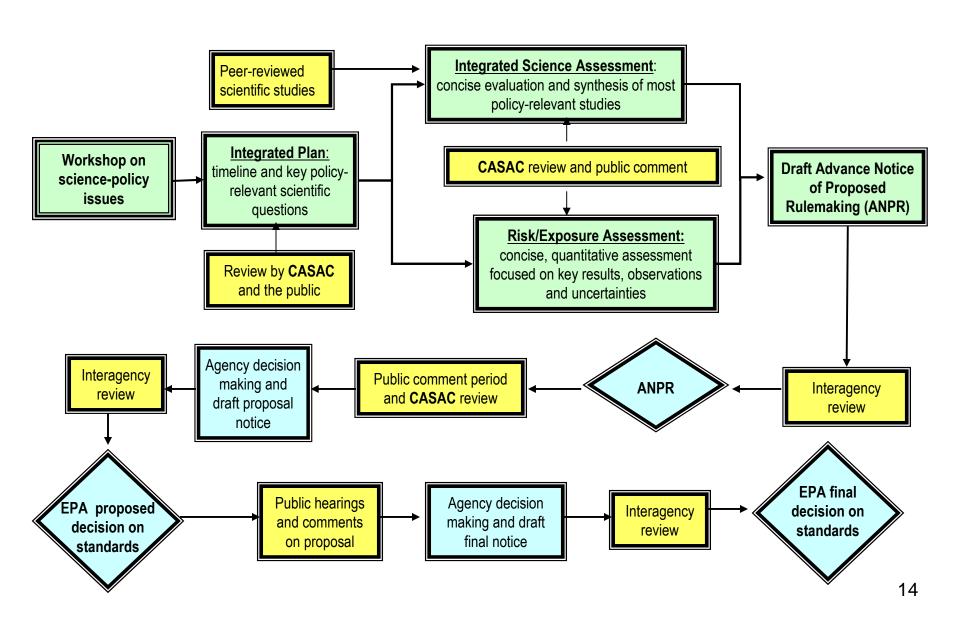
### Risk/Exposure Assessment

- Create more concise document in parallel with development of ISA
- Emphasize key results, observations and uncertainties

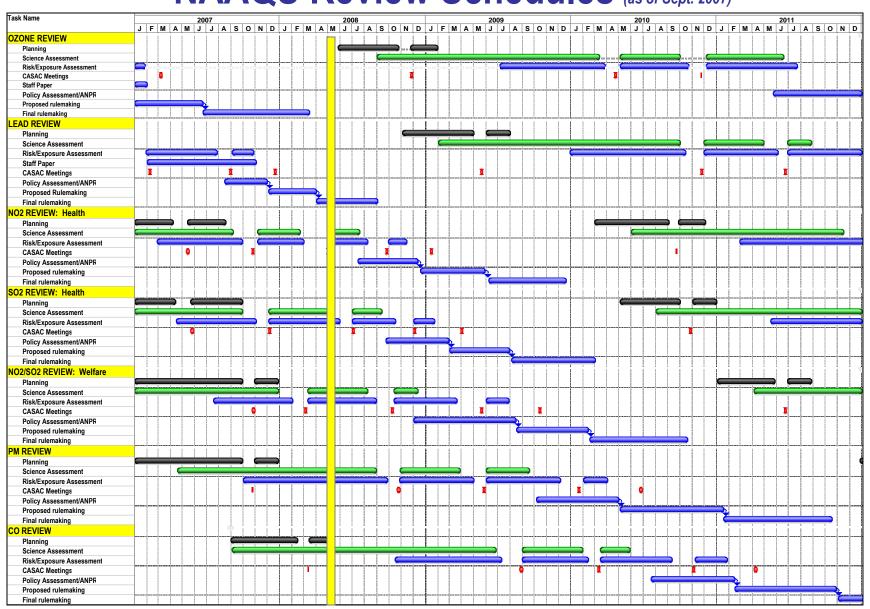
### Policy Assessment/Rulemaking

Develop policy assessment which will present Agency views

# **NAAQS** Review Process



## NAAQS Review Schedules (as of Sept. 2007)



# **Current PM NAAQS Review**

- Overarching questions in primary NAAQS review
  - In light of newly available information, are current standards requisite to protect public health with an adequate margin of safety?
  - If not, what revisions are appropriate in terms of indicator, averaging time, level and form?
- Framework for current review
  - Building on the last review, the evaluation of the available scientific evidence will be based on particle size, considering fine and coarse-fraction particles separately
    - · Evidence for additional size fractions (e.g., ultrafines) will also be considered
    - Within this basic structure, evidence on specific components, sources, and environments (e.g. urban/non-urban areas) will be evaluated
  - Update and expand quantitative risk assessment

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# **Key Policy-Relevant Questions for Current Review**

### Sources/Environments

- What factors influence the variability of PM<sub>10-2.5</sub> mass and composition between locations (including rural & urban differences)?
- Are thoracic coarse particles found in urban and/or rural areas associated with adverse health effects?
- Does the type of health outcome and the magnitude of estimated risk differ between rural and urban areas?
- Do source and compositional differences of PM<sub>10-2.5</sub> affect the type and severity of health outcomes?

### Sensitive/Vulnerable Populations

- Are there specific subpopulations that are more sensitive to PM<sub>10-2.5</sub> exposures? If so, what are the characteristics of these subpopulations (e.g., age, ethnic group, SES)?
- Do differences in PM<sub>10-2.5</sub> components/sources/environments affect who is susceptible to adverse health outcomes?

### Risk/Exposure Considerations

- How do PM<sub>10-2.5</sub> exposures vary spatially and temporally?
- What is the impact of exposure measurement error on effect estimates?

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# **Key PM**<sub>10-2.5</sub> **Monitoring Issues for Current Review**

### Network Design

- What factors should be considered in identifying the number of monitors and geographic distribution of monitors in a PM<sub>10-2.5</sub> network?
- What additional sampling and statistical techniques are available to help determine the minimum number of monitors needed to assess spatial and temporal variability?
- What are the appropriate monitor placement criteria (distance relative to sources, measurement scale, and inlet height)? Should data from monitors located nearly adjacent to sources be excluded from comparison with a potential NAAQS?

### **Monitoring Methods**

- What new information is available to inform options and technologies for sampling and analysis of components of thoracic coarse particles?
  - Currently the difference and dichot methods are being used. What other sampling methods or technologies are available and appropriate for collecting PM<sub>10-2.5</sub>?
  - Do biological materials and fly ashes need to be measured and, if so, how should they be collected and analyzed?

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# **Current PM NAAQS Review: Completed Activities**

- PM: first review following revised NAAQS process from start to finish
- Initial planning workshops July '07
- Integrated Review Plan (IRP)- finalized Mar '08
- Technical documents under development:
  - Integrated Science Assessment (ISA)
    - Authors' workshop to discuss preliminary draft ISA materials June 16-17, '08
    - Submit 1<sup>st</sup> draft for CASAC/public review Sept '08
  - Risk/Exposure Assessments
    - Submit draft Scope and Methods Plans for CASAC/public review Oct '08
  - Next CASAC review early Dec '08
- Studies published through early '09 will be considered in final ISA
- Additional risk/exposure assessment studies published through mid '09 may also be considered

## Schedule for the PM NAAQS Review

(as of April 2008)

Major Milestones  Workshops to Discuss Key Policy- Relevant Issues		Projected/Completed Date July 2007	Projected/Completed CASAC Review Date
Integrated Science Assessment	First Draft Second Draft Final	September 2008 March 2009 September 2009	Early December 2008 — May 2009
Risk/Exposure Assessment	Draft Plan First Draft Second Draft Final	October 2008 April 2009 November 2009 March 2010	Early December 2008  May 2009  January 2010
Policy Assessment/ Rulemaking	ANPR Proposed Final	June 2010 January 2011 October 2011	August 2010

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